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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,816	12/28/2000	Tatsurou Kawamura	43888-092	3440

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EXAMINER

COLE, MONIQUE T

ART UNIT PAPER NUMBER

1743

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/749,816

Applicant(s)

KAWAMURA, TATSUROU

Examiner

Monique T. Cole

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-12 and 14-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-4,8-12 and 14-28 is/are allowed.
- 6) ☒ Claim(s) 1,6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,264,589 to Corey (herein referred to as "Corey '589) in view of USP 4,485,176 to Bollin, Jr. et al. (herein referred to as "Bollin") & USP 5,658,532 to Kuroskai et al. (herein referred to as "Kurosaki").

Corey '589 teaches that a known method for the determination of the presence of protein consists of measuring turbidity following sample acidification. According to this known method, the turbidity of the sample is measured using a spectrophotometer following the addition of a protein-precipitating agent, generally an acidifying agent, to the sample. The calculated turbidity of the sample is compared to the spectrophotometric standard curves to determine the presence of protein in the sample. Common precipitating agents include sulfosalicylic acid, trichloroacetic acid and tannic acid. See col. 1, lines 45-55.

Corey '589 does not expressly teach measuring intensity before and after the addition of tannic acid. However, it would have been obvious to one of ordinary skill in the art to measure the absorbancy before and after the addition of tannic acid in order to generate the spectrophotometric standard curve used to calibrate protein amount. Measuring the sample before the addition of tannic acid would serve as a reference sample and eradicate any unwanted background from the sample. It is well appreciated in the art that a "zeroing" sample be used to

Art Unit: 1743

calibrate the spectrophotometer prior to subsequent measure of samples. This assertion is further exemplified by Bollin, comprising a method of measuring the protein concentration in a sample by differentiating between samples containing turbidity and samples wherein the turbidity-causing reagent was not added (blank). This blank is "particularly useful for the measurement of protein" in turbidity methods because it can "help reduce assay interference" from sample chromogens, bubbles, and the like. Bollin establishes that it is well within the skill of the art to have turbidimetric methods that include both measurement of the absorbance of protein samples both before and after the presence of turbidity.

Further, with regard to claim 7, while Corey '589 does not disclose such a correction procedure, it would have been well within the skill of the art to recognize procedural problems that may lead to a skewed result and have some means to compare the result to that indicative of a problem.

Finally, the combination of Corey and Bollin does not teach that both transmitted light and scattered light intensity is detected in order to determine the protein concentration in the solution. However, Kurosaki teaches that it is conventionally known to measure both scattered and transmitted light to give the optical properties for the analysis of the constituents of bodily specimen (i.e., plasma, urine or others). SEE col. 1, lines 6-9; col. 2, lines 37-45. This would prove helpful because it would be a means to self-check the results to ensure that the same concentration was derived by both optical measurements and would also eliminate error derived from background noise potentially present in any single sample. It would have been obvious to one having ordinary skill in the art to employ this additional optical analysis step in the

Art Unit: 1743

combination method of Corey and Bollin to ensure the accuracy and precision of the protein determination.

Response to Arguments


2. Applicant's arguments with respect to claim 5 and the addition of its limitation into newly amended claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

3. Claims 2, 3, 4, 8-12 and 14-28 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 571-272-1255. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.


Monique T. Cole
Examiner
Art Unit 1743

MC *me*